Development of Systems of Care for ST-Elevation Myocardial Infarction Patients

The Primary Percutaneous Coronary Intervention (ST-Elevation Myocardial Infarction–Receiving) Hospital Perspective

Christopher B. Granger, MD, Co-Chair; Timothy D. Henry, MD, Co-Chair; W. Eric R. Bates, MD, FAHA; Bojan Cercek, MD, FAHA; W. Douglas Weaver, MD; David O. Williams, MD, FAHA

As noted in the previous section of these conference proceedings,[1] there are 3 potential strategies to increase the number of ST-segment myocardial infarction (STEMI) patients with timely access to primary percutaneous coronary intervention (PCI): (1) hospitals currently without PCI capability can develop primary PCI services without cardiac surgery on-site; (2) non–PCI-capable hospitals can rapidly expedite the transfer of STEMI patients to primary PCI-capable hospitals after diagnosis and thereby serve as STEMI referral hospitals; or (3) communities with emergency medical services (EMS) systems can develop prehospital transport protocols that bypass non–PCI-capable hospitals. The best approach for a given community will vary and will be heavily influenced by geographic location and available resources.

In this article, we view these strategies from the perspective of the PCI-capable hospital that "receives" STEMI patients (STEMI-receiving hospital). A primary PCI center is defined as any hospital that performs primary PCI. Patients can present to PCI-capable hospitals through 1 of 3 pathways. Each of these modes of presentation offers opportunities for improving time to treatment and access to primary PCI. The Figure depicts the position of the primary PCI-capable hospital within the system.

The Current System

Patient Presentation to a PCI-Capable Hospital

Door-to-balloon time is a focus for improvement at many hospitals because it is a Centers for Medicare and Medicaid Services quality indicator for STEMI. An efficient emergency department (ED) triage system quickly acquires a 12-lead ECG to diagnose STEMI in patients with suggestive symptoms and rapidly activates the cardiac catheterization laboratory. Door-to-balloon times have been shown to be shorter when the emergency physician is able to activate the cardiac catheterization laboratory without consulting a cardiologist.[2]

Patient Presentation Directly to a PCI-Capable Hospital by EMS

The use of EMS by patients provides the opportunity for prehospital ECG diagnosis of STEMI, as well as notification and activation of the cardiac catheterization laboratory to substantially accelerate door-to-balloon time.[3] Prehospital ECGs can be read by computer algorithms, interpreted by trained paramedics, and/or electronically transmitted to the receiving hospital. Unfortunately, >50% of patients with STEMI arrive at the hospital without using EMS, and prehospital ECGs continue to be underutilized. Diagnosis of STEMI in the prehospital phase potentially allows the use of

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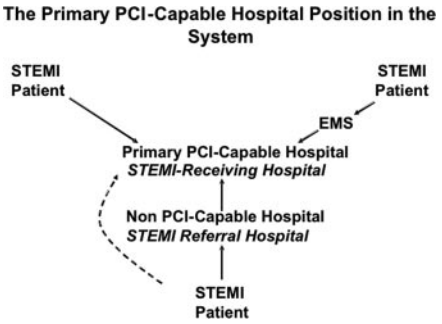

Figure. Primary PCI-capable hospital position in the system.

destination protocols to bypass non–PCI-capable hospitals and directly transport patients to the nearest PCI-capable hospital, as shown by the dotted line in the Figure.

Hospital Transfer to a PCI-Capable Hospital

Several recent randomized trials support the safety and efficacy of transferring STEMI patients for primary PCI from community hospitals that do not have PCI capability.[4–7] A recent meta-analysis of these trials demonstrated a significant reduction in the composite end point of death, reinfarction, and stroke (Table), although there was only a trend for reduction in death.[8] Most of the benefit was in reducing the risk of reinfarction, but this benefit may have been overestimated compared with what would be achieved in most practice settings in the United States, because there was very low use of rescue PCI in the patients initially treated with fibrinolytics (1.9% in the DANish multicenter randomized study of fibrinolytic therapy versus acute coronary angioplasty in Acute Myocardial Infarction [DANAMI]-2).[6] Moreover, patients deemed to be high risk for transfer were excluded, and first door-to-balloon times were faster than in most reports from the United States. In the only randomized trial to compare transfer for PCI to fibrinolytics performed in the United States (a small trial that did not meet its enrollment objectives), the median first door-to-balloon time was 155 minutes despite a mean transfer distance of only 32 miles.[7]

In the National Registry of Myocardial Infarction (NRMI 3-4), only 4.2% of US patients transferred from a non–PCI-capable hospital to a PCI-capable hospital had a door-to-balloon time of within 90 minutes as recommended by the American College of Cardiology (ACC)/American Heart Association (AHA) STEMI guideline.[9] Thus, although the available data support transfer for primary PCI when transfer times and first door-to-balloon times are rapid, questions remain as to the relevance of these data in typical US practice.

Selected Current Model Systems of STEMI Care in the United States

"Hub and Spoke" Systems of Transfer to Primary PCI Centers

The Minneapolis Heart Institute's level 1 myocardial infarction program has the largest reported experiences designed to integrate the care at non–PCI-capable hospitals (STEMI referral hospitals) with a regional PCI-capable hospital (STEMI-receiving hospital). The program includes rural and community hospitals up to 210 miles away from the STEMI-receiving hospital.[10] Key components of the program include (1) empowering the emergency physician (or EMS personnel in certain situations) at the non–PCI-capable hospital to activate the system with a single phone call; (2) the use of a standardized protocol that is simple and systematic; (3) a customized transfer plan for each non–PCI-capable hospital; (4) an in-depth training program for each non–PCI-capable hospital, including EMS, ED, and primary care providers, as well as the local community; (5) a comprehensive quality improvement program; and (6) systems to support the patient and family during the initial hospital stay and on their return to the local community. More than 1345 patients have now been treated with this system, including 297 patients in the STEMI-receiving hospital, 627 patients in 14 hospitals up to 60 miles away (zone 1), and 421 patients in 16 hospitals 60 to 210 miles away (zone 2) from the STEMI-receiving hospital. With this standardized protocol, the median door-to-balloon times from the community STEMI referral hospitals to balloon inflation in the STEMI-receiving hospital were 96 minutes in zone 1 and 118 minutes in zone 2. All patients

TABLE. STEMI Trials of Immediate Fibrinolysis Versus Transfer for Primary PCI

Trial	n	Fibrinolytic Agent Used	First Door-to-Balloon Time, min	Transport Time, min	Death/Reinfarction/Stroke Composite End Point, %		*P*
					PCI	Lytic	
PRAGUE	300	SK	95*	35	8.0	15	<0.02
PRAGUE-2	850	SK	97*†	48	8.4	15.2	<0.003
DANAMI-2	1572	tPA	115	32	8.0	13.7	<0.001
Air PAMI	138	tPA	155	26	8.4	13.6	0.33
Meta-analysis‡	3750				42% Relative risk reduction		<0.001

PRAGUE indicates PRimary Angioplasty in patients transferred from General community hospitals to specialized PTCA Units with or without Emergency thrombolysis; SK, streptokinase; DANAMI, DANish multicenter randomized study on fibrinolytic therapy vs acute coronary angioplasty in Acute Myocardial Infarction; tPA, tissue-type plasminogen activator; and Air PAMI, Primary Angioplasty in Myocardial Infarction.

*Times are median when available.

†Randomization to balloon.

‡Dalby et al[8] also includes the Maastricht and Comparison of Angioplasty and Prehospital Thrombolysis in acute myocardial Infarction (CAPTIM) trials.

were included in the protocol and database, which led to a high-risk cohort with 15% of patients >0 years of age, 12% with cardiogenic shock, and 11% with cardiac arrest before arrival in the cardiac catheterization laboratory. Despite this high-risk unselected cohort, the in-hospital, 30-day, and 1-year mortality rates were 4.2%, 4.9%, and 7.2%, respectively, with no differences between patients presenting for primary PCI at the PCI center, zone 1 hospitals, and zone 2 hospitals.[11]

A statewide approach is being used in North Carolina in the Reperfusion of Acute Myocardial Infarction in North Carolina Emergency Departments (RACE) project, which shares many features of the Minnesota model. The project incorporates standardized protocols and integrated systems for the treatment and timely transfer (when appropriate) of patients with STEMI in 5 geographic regions in North Carolina, which include 70 hospitals, 10 of which are STEMI-receiving hospitals. Although regional centers play a key role in the systems, the goal is not to transfer all patients for primary PCI but rather to also administer fibrinolytic therapy when appropriate according to the ACC/AHA STEMI guideline.[2] This project has been created with an alliance between national and regional professional societies, a local payer (Blue Cross and Blue Shield), industry, and healthcare providers, including EMS, emergency medicine, cardiology, and hospital administrations. The program includes ≈70 hospitals (including 10 STEMI-receiving hospitals). For each hospital, data are collected before and after customized interventions to increase the proportion of eligible patients receiving reperfusion therapy and reduce door-to-balloon and door-to-needle times. The plan includes assessment of the impact of various features on both process and outcomes to allow refinement of strategies for improving application of reperfusion therapy.

Destination Protocols for EMS to Triage to PCI Centers

An urban program has been implemented in Boston, Mass, that involves destination protocols to take STEMI patients directly to qualified PCI-capable hospitals. The Boston EMS has established a "point-of-entry" plan that directly transports STEMI patients to the nearest hospital with primary PCI capabilities.[11] To foster collaboration and better care in the region, the project includes an oversight committee composed of representation from the 9 participating hospitals and a data safety and independent monitoring board that includes 5 Boston cardiologists, 1 outside interventional cardiologist, and 1 statistician. The Boston standards for the PCI-capable hospitals include hospital volumes of at least 36 primary PCI procedures per year, performance of immediate angiography in at least 90% of patients transported, and door-to-balloon times of within 120 minutes (more recently within 90 minutes) in at least 75% of ideal patients (eg, patients who are ideal candidates for primary PCI).

The Ideal System for the STEMI-Receiving Hospital

The current ACC/AHA guideline provides the best available recommendations to guide practice for treatment with primary PCI.[2] The 2004 update of the STEMI guidelines placed a strong emphasis on systems development and integration of aspects of care for which coordination is needed. Ideal systems can enable STEMI-receiving hospitals to expand optimal reperfusion therapy to millions of Americans. Criteria for such an ideal center are proposed below.

Criteria for Primary PCI Centers

The following are criteria for ideal PCI centers,[12] with or without on-site cardiac surgery.

Institutional Resources

1. Primary PCI should be provided as routine treatment for appropriate STEMI patients 24 hours a day, 7 days a week.
2. Primary PCI should be performed as soon as possible. The Door-to-Balloon: An Alliance for Quality Campaign (http://www.acc.org) goal is to achieve a door-to-balloon time of <90 minutes for at least 75% of nontransfer patients with STEMI.
3. All institutions should be able to provide high-quality supportive care for patients with STEMI and its complications, including respiratory failure, congestive heart failure, cardiac arrhythmias, and cardiogenic shock (including intra-aortic capability) on-site.
4. All institutions should have a written commitment by the hospital administration to support the program and be required to:
   A. Identify a physician director of the primary PCI program accountable for defining, implementing, and directing the overall primary PCI program, including responsibility for equipment, personnel, physician competency, privileges, availability, quality assurance, and case review conferences, and
   B. Create a multidisciplinary group with representation from the ED, the quality improvement team, EMS, the coronary care unit, and the cardiac catheterization laboratory that includes physician and nursing leadership and meets regularly to review operational issues and problems to identify and implements solutions.
5. All institutions should design and implement a formal continuing education program that includes practical implementation training for staff.
6. For institutions without surgery on-site, there must be a formal, written agreement with a tertiary institution that provides for rapid transfer of patients for any required additional care, including elective or emergency cardiac surgery or PCI. Furthermore, there must be a written agreement with an advanced cardiovascular life support EMS provider that provides for transport within the shortest time feasible, ideally within 30 minutes of request for transport.

Physician Resources

1. Interventional cardiologists should meet ACC/AHA criteria for competence.[13] These include performing at least 11 primary PCI procedures per year and 75 total PCI procedures per year.
2. Interventional cardiologists should participate in and be responsive to a formal on-call schedule and participate in the other activities described herein.

Program Requirements

1. At least 36 primary PCI procedures and 400 total PCI procedures should be performed annually.

2. The primary PCI program should be described in a "manual of operations." Included should be the standards contained in the ACC/AHA guidelines for management of patients with acute myocardial infarction and guidelines for PCI.[2,13] In addition to policy regarding hours of operation, laboratory staff and physician availability and responsibility, and the process for informed consent, plans for treating recurrent ischemia, reinfarction, and PCI complications should be included.
3. A mechanism for monitoring program performance, process measures, and patient outcomes must be established. This will facilitate ongoing quality improvement activities and provide the opportunity to measure program compliance, effectiveness, and safety. Accordingly, a data set will be required that includes patient demographic and clinical characteristics, and times for symptom onset, initial healthcare system contact, ECG acquisition, catheterization laboratory activation, catheterization laboratory availability, procedure initiation and termination, and achievement of reperfusion and balloon inflation. Procedure outcome and complications and patient clinical outcomes should be recorded.

Other Features of an Ideal System

1. Data collection and feedback: Although Centers for Medicare and Medicaid Services quality measures are focusing on PCI-capable hospital door-to-balloon time, first door-to-balloon time for transferred patients and the proportion of eligible patients receiving some reperfusion therapy need to be included. The NRMI has provided important insights into this problem, but only at participating centers that likely represent better-than-average performance. Feedback to participants in the care process should be timely and complete and should have enough detail to identify specific aspects of care. For example, for a patient transferred for primary PCI, feedback should be provided to the initial transferring hospital as to timing of diagnosis and contact with the PCI-capable hospital, to the EMS personnel and other transfer participants as to transfer times, and to the PCI-capable hospital regarding cardiac catheterization laboratory arrival and balloon inflation time. Although the reviewing of aggregate data at periodic meetings is important to track institutional improvement, the provision of prompt feedback to those involved in the patient's care will enable identification of specific areas for improvement.
2. Prehospital ECG and earliest cardiac catheterization laboratory activation when ST elevation is identified: Linkage of prehospital ECG interpretation (with or without transmission) with cardiac catheterization laboratory activation provides an important opportunity to shorten time delays. Prehospital diagnosis offers the opportunity to bypass non–PCI-capable hospitals and transport patients directly to the PCI-capable hospital. For patients transferred from a non–PCI-capable hospital, a protocol should be in place with defined procedures to minimize the time necessary for the initial diagnosis and transfer to the PCI-capable hospital. Minimizing delay depends on earliest notification within an integrated communication system. This requires EMS training, technology, and communication systems to enable activation to occur as early as possible.
3. ED protocols: Each primary PCI center ED must have standardized STEMI management protocols focused on efficient diagnosis of STEMI, earliest communication, streamlined initial management, and rapid transfer.
4. Single phone call and universal patient acceptance: STEMI referral hospitals should be able to call a single number to notify the STEMI-receiving hospital that a patient needs primary (or rescue) PCI and to activate the cardiac catheterization laboratory. Catheterization laboratory activation and transfer should not depend on cardiology review of the ECG, checking for bed availability, or review with the interventional cardiologist, all of which will result in delays. Ideally, calls should be recorded and reviewed as part of the quality improvement process.

Current Gaps and Barriers

Barriers to Timely Access to Primary PCI

1. Busy PCI hospitals may be required, on occasion, to divert patients to other EDs because of bed availability or lack thereof.
2. Major delays in ED diagnosis of STEMI occasionally occur, especially for patients not using EMS. There needs to be wider application of written protocols for the assessment of all patients with possible ischemic symptoms, early interpretation of the ECG, and initiation of treatment in the ED.
3. Manpower and financial overhead considerations for smaller programs may prevent 24-hours-a-day, 7-days-a-week availability for primary PCI. Even for larger programs, expansion of services to accommodate patients transferred from STEMI referral hospitals or brought directly to the STEMI-receiving hospital by EMS will need to occur.
4. Reimbursements for optimal coordination of EMS services, STEMI referral hospitals, and STEMI-receiving hospitals need to be aligned to reflect the work performed.
5. In most PCI-capable hospitals, cardiac catheterization laboratory physicians and staff are off-site during off-hours. A mandate to assemble the team within 20 to 30 minutes of notification of the impending arrival of a STEMI patient needs to be established.

Recommendations for Research, Programs, and Public Policy

Research

1. Further evaluation of transfer times, cost, and outcomes with interhospital transfer for primary PCI is needed.
2. More information is needed regarding the safety and effectiveness of primary PCI at centers without surgery on-site.
3. Evaluation of the long-term outcome of reducing reinfarction rates after STEMI should be performed. The main advantage of primary PCI compared with fibrinolytic therapy is a reduced rate of reinfarction.
4. Evaluation of the relationship between operator and hospital volumes and patient outcomes should continue.

Programs

1. Novel and expedited methods of patient consent and medical information transfer should be developed.

2. Communication programs for seamless interface with patients and their primary care providers after discharge from the primary PCI center should be developed.

Public Policy

1. Regional transportation systems need to be developed to transport STEMI patients to STEMI-receiving hospitals.
2. Criteria for STEMI-receiving hospitals need to be defined/redefined and included in the ACC/AHA STEMI and PCI guidelines (include protocols, oversight team, competencies of the hospital and caregivers, and collection of process and outcome data).
3. Requirements for a STEMI-receiving hospital need to be defined so that they could be used by payers and possibly The Joint Commission for payment/certification.
4. The public should be educated on the value of calling 9-1-1 and of treatment at STEMI-receiving hospitals.
5. The Centers for Medicare and Medicaid Services should be encouraged to adjust payment to hospitals based on door-to-balloon times of <90 minutes, provision of cardiac rehabilitation services, and prescription for evidence-based medical and lifestyle therapy for STEMI patients.
6. The establishment of regional STEMI-receiving hospitals should be encouraged. The relationship between volume and outcomes is well established for PCI, and it is likely the best results will be obtained when PCI-capable hospitals perform substantial (eg, >100) primary PCI procedures per year.

Disclosures

Potential conflicts of interest for members of the writing groups for all sections of these conference proceedings are provided in a disclosure table included with the Executive Summary.

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